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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/470,026	12/22/1999	YUE-TEH JANG	241/120	5678

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EXAMINER

SIRMONS, KEVIN C

ART UNIT	PAPER NUMBER
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3763

DATE MAILED: 08/13/2003

17

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/470,026

Applicant(s)

JANG ET AL.

Examiner

Kevin C. Sirmons

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 June 2003.
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 21, 43-46 and 50-54 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 21, 43-46 and 50-54 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 21 and 50-54 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nash et al. U.S. Pat. No. 6,080,170.

Nash discloses a method for treatment of a vascular lesion, comprising the steps of introducing a guide wire into a vessel, the guidewire having an expandable occlusive member disposed on a distal end thereof (figs. 16 and 17; cols. 26-29); advancing the guidewire to a region of interest and positioning the occlusive member distally of the region of interest (figs. 16 and 17; cols. 26-29); advancing a catheter with an expandable stent over the guidewire and positioning the stent within the region of interest (figs. 16 and 17; cols. 26-29); expanding the occlusive member (figs. 16 and 17); expanding the stent within the region of interest (figs. 16 and 17); and aspirating fluid and embolic debris from the region of interest (figs. 16 and 17; cols. 26-29) wherein the step of aspirating fluid and embolic debris comprises the steps of infusing fluid into the region of interest through an infusion lumen and one or more infusion ports disposed on the aspiration catheter and suctioning the fluid and embolic debris from the region of interest through one or more suction lumens in fluid communication with a vacuum (figs. 16 and 17; cols. 26-29); as to claim 50-54, (figs. 16 and 17).

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Nash does not clearly disclose advancing an aspirating catheter over the guidewire and positioning the aspiration catheter proximal the region of interest. Nevertheless, it is the examiner position that during treatment of a vascular lesion the system may require adjustments to various parts including adjusting (advancing and/or withdrawing) the aspirating catheter (24) over the guidewire. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to advance the aspirating catheter over the guidewire and position the aspiration catheter proximal the region of interest to ensure a proper fit of the distal end of the aspiration catheter (24) against the walls of the vascular system thereby preventing any fluid from escaping between the outer wall of the aspiration (24) and the inner wall of the vasculature during the aspiration procedure.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 43-46 are rejected under 35 U.S.C. 103(a) as being obvious over Nash et al in view of Imran U.S. Pat. No. 5,833,650.

Nash discloses the method of for treatment of vascular lesion substantially as claimed except for wherein the expandable stent is a self-expandable stent, shape memory material, thermally adapted to expand at or near body temperature and comprises Nitinol.

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Imran discloses a self-expandable stent, a stent made from shape memory material such as Nitinol and a stent that is thermally adapted to expand at or near body temperature. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the stent of Nash to have the above features of Imran in order to ensure that restenosis will not take place (col. 8).

Response to Amendment

The amendment to the claims filed on 12/18/02 does not comply with the requirements of 37 CFR 1.121(c) because it appears that applicant did not consider the pre-amendments that he made on 10/25/01 paper no. 1 where Applicant deleted the limitation "advancing an aspirating catheter over the guidewire and positioning the aspiration catheter proximal the stent". The aforementioned limitation was not considered because it was not properly underlined as required by 37 CFR 1.121 ©. Amendments to the claims filed after March 1, 2001 must comply with 37 CFR 1.121(c) which states:

(c) Claims.

(1) Amendment by rewriting, directions to cancel or add: Amendments to a claim must be made by rewriting such claim with all changes (e.g., additions, deletions, modifications) included. The rewriting of a claim (with the same number) will be construed as directing the cancellation of the previous version of that claim. A claim may also be canceled by an instruction.

(i) A rewritten or newly added claim must be in clean form, that is, without markings to indicate the changes that have been made. A parenthetical expression should follow the claim number indicating the status of the claim as amended or newly added (e.g., "amended," "twice amended," or "new").

(ii) If a claim is amended by rewriting such claim with the same number, the amendment must be accompanied by another version of the rewritten claim, on one or more pages separate from the amendment, marked up to show all the changes relative to the previous version of that claim. A parenthetical expression should follow the claim number indicating the status of the claim, e.g., "amended," "twice amended," etc. The parenthetical expression "amended," "twice amended," etc. should be the same for both the clean version of the claim under paragraph (c)(1)(i) of this section and the marked up version under this paragraph. The changes may be shown by brackets (for deleted matter) or underlining (for added matter), or by any equivalent marking system. A marked up version does not have to be supplied for an added claim or a canceled claim as it is sufficient to state that a particular claim has been added, or canceled.

(2) A claim canceled by amendment (deleted in its entirety) may be reinstated only by a subsequent amendment presenting the claim as a new claim with a new claim number.

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Response to Arguments

Applicant's arguments with respect to claims 21, 43-46 and 50-54 have been considered but are moot in view of the new ground(s) of rejection.

In response to applicant's argument the examiner is unclear as to the direction and/or totality of the arguments. However, the examiner is clear about applicant's conclusion. Therefore, the examiner will respond as best understood.

Clearly a guidewire is introduced into a vessel, the guidewire having an expandable member disposed on a distal end (124); advancing the guidewire to a region of interest and positioning the occlusive member distally of the region of interest (col. 27, lines 53-65); advancing a catheter (not shown and col. 28, lines 29-33) with expandable stent over the guidewire and positioning the stent within the region of interest (col. 28, lines 29-42); expanding the occlusive member (col. 28, lines 25-28); expanding the stent within the region of interest (col. 28, lines 29-42); and aspirating fluid and embolic debris from the region of interest (col. 28, lines 32-63).

The examiner has found that amendment filed on 12/18/02 was improper since applicant did not underline the additional subject matter to the claim 21.

Conclusion

Applicant's amendment (12/18/02) paper no. 12 necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communication from the examiner should be directed to Kevin C. Sirmons whose telephone number is (703) 306-5410. The examiner can normally be reached on Monday - Thursday from 6:30 am to 4:00 pm. The examiner can also be reached on alternate Fridays.

KCS

Kevin C. Sirmons
Patent Examiner
8/11/03

Brian L. Casler

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